UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

VALUE DRUG COMPANY Plaintiff, - against - TAKEDA PHARMACEUTICALS, U.S.A., INC., *et al.*, Defendants.	Hon. Mark. A. Kearney Civil Action No. 2:21-cv-03500-MAK ORAL ARGUMENT REQUESTED

DEFENDANTS WATSON LABORATORIES, INC. AND AMNEAL PHARMACEUTICALS LLC'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT

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Plaintiff's opposition brief defends a complaint that Plaintiff did not file, and only highlights the pleading failures of the complaint that Plaintiff actually did file. This Court should dismiss the claims asserted against Watson and Amneal because the allegations contained in the complaint Plaintiff actually filed are inadequate to state any plausible claims. It goes without saying that Plaintiff cannot now amend its complaint through its opposition brief, but even if the Court were to consider Plaintiff's new theory of wrongdoing, the claims still should be dismissed because settling patent litigation in exchange for an early-entry date into a market with at least three generic competitors, without more, is not a plausible violation of the Sherman Act.

The Court should also deny Plaintiff's belated request for leave to amend its complaint. Plaintiff refused to amend its complaint when originally directed to do so—despite being on notice of the pleading deficiencies long before that deadline. If the Court does grant leave to amend, Watson and Amneal respectfully request that the costs of the instant motion to dismiss (directed at factual allegations Plaintiff concedes are inaccurate) be assessed against Plaintiff.

I. PLAINTIFF PLED FACTS IT KNEW TO BE UNTRUE, REFUSED TO AMEND, AND NOW DEFENDS AN (EQUALLY IMPLAUSIBLE) UNPLEADED THEORY.

Plaintiff's complaint alleges that in exchange for defined periods of exclusive generic sales, supposedly worth approximately $12–$36 million to each co-conspirator, Watson and Amneal unlawfully agreed to delay entry into the generic colchicine market. *See* Br. at 5–7, 12 (explaining the complaint's theory of the case). Specifically, the complaint alleges that "Takeda struck agreements with Watson and Amneal, respectively, offering each a defined time, believed to be between 6 and 18 months in duration, to sell generic Colcrys *free from competition from all other generic Colcrys sellers*." Compl. ¶ 56 (emphasis added). According to Plaintiff, that serial exclusivity is a "basic feature[]" of the alleged unlawful agreement, *id*. at ¶ 54, and the only reason (alleged in the complaint) that Watson and Amneal stood to gain financially from

participating in the conspiracy. Exclusivity—*i.e.*, being the only generic on the market—was crucial because according to Plaintiff, if even three generics were sold at one time, there would be a complete "price collapse." *Id.* at ¶¶ 58–60.

As Plaintiff now concedes, its allegation of serial exclusivity is wholly contradicted by the written agreements between each of the alleged co-conspirators. Because there was never any plausible period of exclusive sales, there also never was any plausible financial reward of $12–$36 million for each alleged co-conspirator. *Contra id.* at ¶ 71 (pegging that range as the value of the now-abandoned "respective periods as the only generic seller on the market"). So as Watson and Amneal explained, Plaintiff's entire theory for what Watson and Amneal supposedly stood to gain from engaging in an unlawful conspiracy is factually inaccurate, making Plaintiff's complaint completely implausible. *See* Br. at 9–14.

Instead of explaining why the factual allegations contained in its complaint state a plausible claim, Plaintiff devotes pages of its opposition to defending its new (and different) theory that Watson and Amneal conspired to violate the Sherman Act because "each received an agreed 135 days of generic Colcrys sales free of competition from firms *other than the co-conspirators*." Op. Br. at 1 (emphasis added). In other words, Plaintiff's new theory is that Watson and Amneal supposedly violated the Sherman Act by settling patent litigations and negotiating to obtain the right to sell generic Colcrys for 135 days in a "limited competition" market containing at least three (but likely four, or more) generic products.[1] *Id.* at 6, 13 n.20. Far from the repeated allegations in the complaint that the Watson and Amneal agreed to enter an output-restriction conspiracy in exchange for allegedly lucrative exclusivity, *see, e.g.*,

[1] The three competitors would be Watson's and Amneal's ANDA generics and Takeda's authorized generic (sold by Par). Of course, Par also was entitled to launch its own ANDA product upon Watson or Amneal's launch, in which case the market would likely have at least four generics: Watson, Amneal, and Par's ANDA generics, and Takeda's authorized generic. *See* Br. at 10–11.

Compl. ¶¶ 4, 71, Plaintiff's theory now is that Watson and Amneal did so simply to get a "better deal" than some other potential generic manufacturers, Op. Br. at 6.

Plaintiff tries to sweep these inconsistencies under the rug by claiming (in a footnote) that the "concurrent[]" or "consecutive[]" nature of the "periods of limited competition" is irrelevant, and any inconsistency between the complaint and the written agreements "fails to detract from the gravamen or plausibility of this case." *Id.* at 13 n.20. Even if the concept of a "concurrent[]" period of exclusivity made sense (it does not), it should be obvious that a period of wholly exclusive generic sales (what is alleged in the complaint) is fundamentally different from a period of "limited competition" among three generic sellers (what is defended in the opposition brief). Under Plaintiff's own allegations, having that many generics on the market would result in a complete "price collapse." Compl. ¶ 58. Plaintiff's own complaint recognizes that the plausible value of sales during a period of exclusivity is materially different from the plausible value of sales during the period of "limited competition" envisioned in the opposition brief, notwithstanding Plaintiff's unpleaded back-of-the-envelope calculations. Op. Br. at 12. That difference is not simply an "immaterial error[]," as Plaintiff implies. *Id.* at 13 n.20.

II. PLAINTIFF FAILS TO ALLEGE THAT WATSON OR AMNEAL ENTERED INTO AN UNLAWFUL AGREEMENT.

Plaintiff attempts to use its opposition brief to re-imagine its case in an attempt to account for the inconsistencies between its complaint and Watson and Amneal's actual written agreements. Plaintiff may not amend its complaint in its briefing, and the Court should dismiss the implausible claims actually pled. And even if Plaintiff were permitted to replead this way, it still fails to come up with a viable unlawful conspiracy.

A. Plaintiff impermissibly seeks to amend its complaint by brief.

This Court should reject Plaintiff's attempt to untether itself from the plainly inadequate allegations in its actual complaint by presenting a new theory in its opposition brief. "[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Pa. ex rel. Zimmerman v. PepsiCo, Inc*., 836 F.2d 173, 181 (3d Cir. 1988) (quoting *Car Carriers, Inc. v. Ford Motor Co*., 745 F.2d 1101, 1107 (7th Cir. 1984)). More than three decades ago, in the context of another antitrust case, the Third Circuit made clear that "[i]n a Rule 12(b)(6) motion . . . the district court should look only to the complaint's averments," and a plaintiff's "legal theories set forth in [a] brief are helpful only to the extent that they find support in the allegations set forth in the complaint." *Id*. That is because "[i]t is one thing to set forth theories in a brief; it is quite another to make proper allegations in a complaint." *Id*. Simply put, a plaintiff's "rights rise no higher than the facts it has alleged, and . . . defendants cannot be said to have violated the antitrust laws in ways that have not been alleged." *Id*. at 180; *Hughes v. United Parcel Serv., Inc*., 639 F. App'x 99, 104 (3d Cir. 2016) (similar); *Tobias v. United States*, 2014 WL 6693721, at *2 (D.N.J. Nov. 26, 2014) ("[I]t is well-established that a Plaintiff cannot amend his Complaint by way of a brief in response to a motion to dismiss."); *Angino v. Wells Fargo Bank, N.A*., 2016 WL 787652, at *11 (M.D. Pa. Feb. 19, 2016), *aff'd*, 666 F. App'x 204 (3d Cir. 2016) ("[P]laintiffs suggest in their opposition to this motion that they may be able to allege such facts, [but] the difficulty with these belated assertions is that they are not set forth in the complaint and run afoul of the well-settled principle that a plaintiff cannot amend a complaint through the filing of a brief, or through arguments set forth in a brief opposing a dispositive motion."); *accord Associated Gen. Contractors of Cal. v. Cal. State Couns. of Carpenters*, 459 U.S. 519, 526 & n.11 (1983) ("As the case comes to us, we must assume that the [plaintiff] can prove the facts alleged in its amended complaint. It is not, however, proper to

assume that the [plaintiff] can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged.").

Plaintiff's attempt to amend its complaint through its opposition brief is particularly brazen because Plaintiff elected *not* to amend its complaint at the designated time. Plaintiff had the settlement agreements contradicting the "basic feature" of its alleged unlawful agreement long before the October 1, 2021 deadline for Plaintiff to file an amended complaint. If Plaintiff intended to rely on its new theory that each of Watson and Amneal violated the Sherman Act simply by getting a "better deal" in its patent settlements than other sellers of generic Colcrys, it had ample opportunity to amend its complaint and add factual allegations in an attempt to allege such a theory based on a 135-day period of "limited competition." It chose not to, so should face the consequences of that choice.

B. Plaintiff's novel theory does not salvage its implausible complaint.

Plaintiff's "opposition brief theory" is that Watson and Amneal agreed to delay selling generic Colcrys for several years in exchange for the right to sell generic Colcrys for 135 days in a market containing at least three and likely four other sellers of a generic product before the market fully genericized. Op. Br. at 6. According to Plaintiff's opposition, this (unpleaded) unlawful agreement to "order[] market entry" was worth approximately "$22.63 million" to both Watson and Amneal. *Id.* at 3, 12.

As an initial matter, Plaintiff's theory is wrong as a matter of law. A "market ordering" achieved through licensing is lawful and fully within the rights of a patent holder so long as the patent holder does not accomplish that ordering through the use of an unlawful and anticompetitive reverse payment. *See generally F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013); *id.* at 150 (citing *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163 (1931), in which "the Court upheld cross-licensing agreements among patentees that settled actual and impending patent

litigation"). But here, Plaintiff does not even attempt to allege that Amneal or Watson received an unlawful reverse payment by, for example, alleging that any value Amneal or Watson received through the settlement agreement was large and unjustified. *Id*. at 158. In fact, at the September 14, 2021 pretrial conference before Judge Savage, Plaintiff specifically disclaimed that it was asserting a reverse payment claim at all.

Plaintiff's disclaimer was appropriate given that the complaint is devoid of any factual allegations to support such a claim, which is fatal to a reverse payment theory. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251–52 (3d Cir. 2017) ("[T]o survive a motion to dismiss when raising an antitrust violation under *Actavis*, "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*." (quoting *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016)). Plaintiff is not credible when it suggests that the $12–$36 million of unlawful profit alleged in the complaint—which the complaint expressly linked to the now-disproven 6 to 18 months of purported *exclusivity*, *see* Compl. ¶ 71—was actually meant to include the profit from the 135-day "limited competition" theory Plaintiff now presents for the first time. *Contra* Op. Br. at 13. Nowhere—either in the complaint or its opposition—does Plaintiff allege any actual facts to support the "value" to Watson or Amneal that this period of 135-day "limited competition" had, and that is reason alone to disregard it.

The most Plaintiff can muster is a back-of-the-envelope calculation by its counsel that purports to estimate the supposed value of the 135-day "limited competition" period, but that calculation suffers from two fundamental—and intentionally misleading—flaws. *First*, Plaintiff's counsel's calculation is based on the erroneous premise—unsupported by any allegations in the complaint—that, absent the settlement agreements, Watson and Amneal would

have entered the market for generic Colcrys on December 29, 2018 (after the conclusion of Par's 180-day exclusivity), and that six other market participants would have entered the market at that same time. *See* Op. Br. at 2 n.5 (listing the so-called "Second Wave" companies); *see also id.* at 12 (calculating value of 135-day period against baseline with a total of nine market participants). The FDA website that Plaintiff itself relies on belatedly to compile the "Second Wave" confirms that none of those companies had even obtained approval to sell generic Colcrys by the time Watson and Amneal supposedly would have entered the market but-for the allegedly unlawful agreements.[2] One of these Second Wave companies—Hetero—was not even approved to sell generic Colcrys until a week after *this suit* was filed. There is no basis to believe that there would have been nine market participants at the relevant time, and certainly Plaintiff has not alleged as much in its complaint.

Second, even accepting this unsupportable premise, Plaintiff's anemic calculation of the benefit of selling the product for 135 days with three competitors versus nine competitors is a red herring. The real question for assessing "a pecuniary motive for [Watson and Amneal] to join the conspiracy," *id.* at 11, is whether Watson and Amneal would make more money selling their generic for less time (*i.e.*, agreeing to delay entry for over 21 months, *see id.* at 3) but with the benefit of 135 days of limited competition upon entry (this is the settlement agreement), than they would selling the product for those additional 21 months, but with full competition from the start (this is Plaintiff's but-for world). Recalculating Plaintiff's counsel's computation using their own assumptions, but reflecting the extra 21 months of sales that Watson and Amneal would have by launching in December 2018, and excluding *only* Hetero (which was not

[2] The approval dates are: Alkem Labs Ltd. - 02/08/2019; Zydus - 02/19/2019; Dr. Reddys - 09/06/2019; Mylan - 09/16/2019; Granules - 02/05/2020; Hetero Labs - 08/13/2021. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=022352 (cited in Opp. at 3 n.5). Nor is there any reason to believe that these companies, who are not alleged to be conspirators, would have had any incentive to delay obtaining approval as expeditiously as possible.

approved to sell until three months ago) but leaving the other 5 additional sellers (again, none of whom could have launched in December 2018), shows that Watson and Amneal would have made at least $1.2 million *more* by launching early without the settlement agreements.[3]

This completely undermines the core premise of Plaintiff's new invented theory that Watson and Amneal stood to earn "more under the output-restriction conspiracy as compared to without the conspiracy," *id.* at 12, and that their "actions only make sense if the output-restriction conspiracy existed and allowed Defendants to benefit from the restrict competition it wrought," *id.* at 13, because neither Amneal or Watson benefitted from—and so had no plausible motive to conspire to achieve—the so-called delayed entry. And Plaintiff's failed mathematical jujitsu exposes the implausibility of its argument that the few facts it *did* plead in its complaint—including the $12–$36 million profit range—are remotely compatible with its new theory.[4]

[3]

Watson and Amneal each as 1 of 3 generics for 135 days under the alleged conspiracy (starting Oct. 15, 2020 ending Feb. 27, 2021)	**Watson and Amneal each as 1 of 8 generics for 791 days without the alleged conspiracy (starting Dec. 29, 2018 and ending Feb. 27, 2021)**
Total annual brand Colcrys sales = $546MM	Total annual brand Colcrys sales = $546MM
Generic volume = 90% = $491.4MM	Generic volume = 90% = $491.4MM
3-generic price % of brand price = 44% = $216.21MM	8-generic price % of brand price = 21% (source: Dkt. No. 119, Gerstein Decl. Ex. A) = $103.19MM
135 days instead of 365 = 37% = $80MM	791 days instead of 365 = 216% = $222.89MM
Each generic gets one third = 33.33% = $26.66MM	Each generic gets one eighth = 12.5% = $27.86MM
Lost dollar sales for each of Watson and Amneal under the supposed conspiracy: **$1.2MM**	

[4] It is also worth pointing out that Plaintiff's new theory evokes a caricature of a Bond super-villain who haughtily lays bare his plot, thereby allowing it to be foiled. It suggests that Watson and Amneal (along with Takeda and Par) conspired to violate the Sherman Act, memorialized the entirety of their (unlawful) agreements in writing, thereafter presented the key (unlawful) terms of their written agreements to a federal judge, and then repeatedly discussed those terms openly in yet another federal court. Op. Br. at 6 (recognizing that Takeda acknowledged the "better deal" received by Watson and Amneal to federal judge); *id.* at 7 (acknowledging Par's similar statements to federal judge). But if Watson, Amneal, and the other Defendants conspired to violate the Sherman Act by obtaining a "better deal," it is implausible that they would then openly tout those precise terms of their unlawful agreements in multiple federal courts. This only further undermines the plausibility of Plaintiff's (unpleaded) theory that the 135-day "limited competition" period constitutes an unlawful agreement in violation of the Sherman Act.

III. LEAVE TO AMEND SHOULD BE DENIED OR, IN THE ALTERNATIVE, CERTAIN COSTS SHOULD BE AWARDED.

Despite deciding not to amend its complaint at the time permitted by this Court, Plaintiff now seeks leave to file an amended complaint should this Court dismiss the operative complaint. *Id.* at 20. Leave to amend should be denied where there are "repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment." *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993). Plaintiff already had an opportunity to amend its pleadings after it received the written settlement and license agreements. Plaintiff intentionally and strategically squandered this opportunity, and the Court need not afford it another chance to amend—particularly where Plaintiff elected to prosecute a complaint that it knew to be factually inaccurate in light of the written agreements. And no amendment can cure the fundamental flaws in Plaintiff's haphazard legal theories, which rest on a wholly implausible conspiracy.

If the Court does grant Plaintiff leave to amend its complaint, Watson and Amneal respectfully request that the Court award attorneys' fees in the amount of the cost to Watson and Amneal of filing the instant motion to dismiss, which was directed to the allegations asserted in a complaint that Plaintiff knew to be factually inaccurate and that Plaintiff apparently had no intention to defend. Plaintiff's failure to amend its complaint before this Court's October 1, 2021 deadline despite having all necessary information to do so "unreasonably" "multiplie[d] the proceedings," thereby causing Watson and Amneal to incur substantial costs in moving to dismiss allegations that Plaintiff never intended to stand by. 28 U.S.C. § 1927. This Court has inherent and statutory power to shift fees in such circumstances. *See id.* ("Any attorney or other person admitted to conduct cases in any court of the United States . . . who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such

conduct."); *Roadway Express, Inc. v. Piper*, 447 U.S. 752, 765–67 (1980). Watson and Amneal respectfully request that the Court do so here if it grants Plaintiff leave to amend.

CONCLUSION

For the foregoing reasons, Defendants Watson and Amneal respectfully request that this Court dismiss Plaintiff's claims against them pursuant to Federal Rule of Civil Procedure 12(b)(6).

Dated: November 19, 2021

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CERTIFICATE OF SERVICE

I, Karl Gunderson, hereby certify that on November 19, 2021, I served the foregoing Defendants Watson Laboratories, Inc. and Amneal Pharmaceuticals LLC's Reply Memorandum of Law in Further Support of its Motion to Dismiss Plaintiff Value Drug's Complaint by electronically filing this document with the Clerk of Court using the CM/ECF system, which will send an electronic notice to the registered participants as identified on the Notice of Electronic Filing.

Dated: November 19, 2021

/s/ Karl Gunderson
Karl Gunderson